MAR 21 2001

K00-3971
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SUMMARY OF SAFETY AND EFFECTIVENESS

General Company Information

Name: Axya Medical, Inc.

Address: 100 Cummings Center
Suite 444C
Beverly, MA 01915

Telephone: (978) 232 - 9997
Fax: (978) 232 - 9998

General Device Information

Product Name: Model 1000 AxyaLoop™ Bone Anchor

Classification: "Non-degradable soft tissue fixation fastener", Product code: MBI Class II

Predicate Devices

Arthrex Inc. FASTak® Suture Anchor [501(k) Number K960516]

Linvatec Corp. Revo® and Mini-Revo® Bone Anchor Fixation System [510(k) Numbers K953954 and K963932]

Description

The device described in this submission is designed with a corkscrew style thread and will be made available initially in two sizes (diameters) specifically for use in shoulder repairs, including Bankart lesion repairs. The Axya Bone Anchor will be made available as a system together with a drill bit, a delivery/extraction handle and a drill guide. These accessories are the same types of instruments included in procedure sets for currently marketed bone anchor systems. Axya Medical believes that the accessory instruments are Class I Manual Surgical Instruments and are exempt from the premarket Notification regulations. The Axya Model 1000 AxyaLoop Bone Anchor is prethreaded with size 2 USP polypropylene monofilament suture material. The suture is a legally marketed material, manufactured by one of several contract suppliers.

The Model 1000 Bone Anchor is designed to be used in both standard open surgical procedures and in minimally invasive (arthroscopic) surgical procedures.

Indications

The Axya Model 1000 AxyaLoop™ Bone Anchor is indicated for securing synthetic monofilament non-absorbable suture to bone. This device is intended for use in repair of recurrent dislocation of the shoulder where the anchor is placed through the metaphyseal cortex such as in the case of a Bankart lesion repair procedure. A minimum of two anchors should be used in a procedure.

Substantial Equivalence

This submission supports the position that the Axya Model 1000 AxyaLoop Bone Anchor is substantially equivalent to a number of previously cleared devices, including the Arthrex Inc. FASTak® Suture Anchor [501(k) Number K960516] and the Linvatec Corp. Revo® and Mini-Revo® Bone Anchor Fixation System [510(k) Numbers K953954 and K963932].

The 510(k) Notice contains summaries of *in vitro* studies which were conducted to evaluate the anchor pull-out strength as specified in the FDA Guidance Document for Testing Bone Anchor Devices (dated April 20, 1996).

The data presented demonstrate that the anchor pull-out force of the Axya Model 1000 AxyaLoop Bone Anchor compared favorably with the predicate device of similar corkscrew geometry (Linvatec Mini-Revo). The failure mode observed for the Axya anchor was predominately anchor pull-out (9 of 10 samples) while the failure mode for the predicate anchor was predominately eyelet fracture (9 of 10 samples). Further, the pull-out force of the Axya anchor was equivalent to the highest forces demonstrated in a published comparison of more than twenty currently marketed bone anchors. The Notice contains a summary report of the observations noted above and a copy of the referenced publication.

The single-patient-use components of the bone anchor system are provided sterile. The suture material and bone anchors are sterilized by a process equivalent to the process used by the original suture manufacturer.

Axya Medical, Inc. believes that the information provided establishes that similar legally marketed have been used for the same clinical applications as the Axya Model 1000 AxyaLoop Bone Anchor. The materials from which the Axya device is fabricated have an established history of use in medical applications, and devices produced by Axya have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2001

Mr. Howard L. Schrayer
Axya Medical, Inc.
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

Re: K003971
Trade Name: Model 1000 AxyaLoop™ Bone Anchor
Regulatory Class: II
Product Codes: MBI, HWC, GAS
Dated: December 21, 2000
Received: December 22, 2000

Dear Mr. Schrayer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhous

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003971

Device Name: Axya, Model 1000 AxyaLoop™ Bone Anchor

Indications For Use:

The Axya Model 1000 AxyaLoop™ Bone Anchor is indicated for securing synthetic monofilament non-absorbable suture to bone. This device is intended for use in repair of recurrent dislocation of the shoulder where the anchor is placed through the metaphyseal cortex such as in the case of a Bankart lesion repair procedure. A minimum of two anchors should be used in a procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003971

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)